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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,338	10/30/2001	Robert W. Stadler	P-7837.00	3322

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EXAMINER

LAYNO, CARL HERNANDZ

ART UNIT PAPER NUMBER

3762

DATE MAILED: 12/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/002,338

Applicant(s)

STADLER ET AL.

Examiner

Carl H. Layno *Carl H. Layno* 11/25/03

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-22 and 24-54 is/are allowed.
- 6) ☒ Claim(s) 55-59 is/are rejected.
- 7) ☒ Claim(s) 23, 60 and 61 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4, 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. Acknowledgment is made of applicant's Information Disclosure Statements (PTO-1449) which were received by the Office on February 15, 2002 and on September 22, 2003. These documents have been made of record in the file as Paper Nos.4 and 6, respectively.

Drawings

2. The formal drawings were received on January 23, 2002. These drawings are approved by both the Draftsperson and the Examiner.

Claim Objections

3. Claim 23 is objected to because of the following informalities:

-In line 8, the words "the and left right atrium" appears to be a typographical error. To overcome this objection, the Examiner recommends changing this to "the left and right atrium".

Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who

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has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 55-59 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Smith '699-B1.

The Smith '699-B1 patent recites a system including an implantable medical device (IMD) 10 (Fig.4) including the use of a plurality of ultrasonic sonomicrometer transducers 60 positioned at various locations around the heart for measuring a physical parameter of the heart and using this parameter to adjust the operation of the IMD 10. In operation, the transducers 60 monitor and send signals to an implanted electronics module 58 (col.7, lines 36-37) containing a ventricular assist device controller 54. The signals processed by controller 54 include distance data (col.7, lines 40-41 and 59-60). Controller 54 then sends control information to IMD 10 (in this case a ventricular assist device).

In regard to claims 56 and 57, the piezoelectric crystals (i.e. sonomicrometer crystals) can be attached to the leads (plural) of a pacemaker (col.8, lines 30-38) to assist in the acquisition of "computed data" parameters used in altering the pacemaker's functionality (col.8, lines 59-66).

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In regard to claim 58, the claimed structures of a “sensor” and “delivery circuit” read upon the modified pacemaker of Smith (col.8, lines 30-67), as set forth *supra* for claims 56-57 if it is assumed that the pacer is a dual-chambered pacemaker capable of pacing both the right atrium and right ventricle. Though the type of pacemaker used by Smith ‘699-B1 is not specified, the use of a dual-chamber pacemaker would have been an obvious, if not inherent, choice given its widespread use and availability.

Allowable Subject Matter

6. Claims 60-61 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. Claims 1-22 and 24-54 are allowed.

8. The following is a statement of reasons for the indication of allowable subject matter:

Independent claims 1, 15, 18, 21, 24, 28, 42, 45, 49, and 51-53 all recite methods and apparatus claims pertaining to a plurality of medical functions involving implantable leads bearing sonomicrometer crystals to measure distances within the body. All of these claims recite the feature of “periodically energizing” the sonomicrometer crystals to generate an ultrasonic frequency emitted signal. The references of the prior art fail to teach this feature. Specifically, the Smith ‘699-B1 patent, cited *supra*, activates its sonomicrometers “continuously, or only during diagnostically relevant times” – not “periodically”, as claimed by the applicant. The

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Kresh et al '304 patent, cited by the applicant as prior art, is the only other patent which specifically mentions the use of an implantable pacemaker with a sonomicrometer sensor (col.4, lines 24-28). Unlike applicant's device, however, that of Kresh et al only recites the use of one endocardial electrode, which is used for pressure sensing, not sensing distances within the heart. Although many prior art patents cited by the applicant recite the use of sonomicrometer sensors used in the heart (Hunyor et al '375-A1, Pitsillides et al '656, Mueller '540, Vesely et al '638, '298), none of these recite specific use with an implantable pacemaker in the manner claimed by the applicant. As a result, the Examiner deems these claims and their depending claims to be allowable.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The Budd et al '611 patent is cited for its pertinent teachings of a distance measuring catheter with sensors located in a patient's heart. Unlike applicant's device, the sensors are not sonomicrometer crystals nor is the catheter attached to an implantable medical device, as required by the applicant.

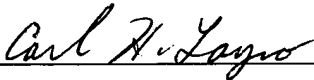
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (703) 308-3694. The examiner can normally be reached on Monday thru Thursday from 9 AM to 6 PM and every

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other Friday between 9AM and 5PM. A voice mail or E-mail message (carl.layno@uspto.gov) may be left if desired.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes, can be reached on (703) 308-5181. All faxed communications should be sent to the Office's new Official FAX number (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Legal Instruments Examiner (LIE) Brenda Webb whose telephone number is (703) 305-7520.



CARL LAYNO
PRIMARY EXAMINER

CHL
11/25/03